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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,252	CROZE ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-21 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group restriction:

I. Claims 1-4 and 6-14, drawn to a method of potentiating the effects of a type I IFN on a target cell population comprising increasing the number of functional IFNAR2c receptor chains on the surface of modified cells within the target cell population and then exposing the modified cells to a therapeutically effective amount of a type I IFN, wherein the up-regulation of gene expression of the IFNAR2c gene is accomplished by introducing an exogenous gene encoding the IFNAR2c polypeptide, classified in class 514, subclass 44.

II. Claims 1-3, 5, 6-9 and 12-13, drawn to a method of potentiating the effects of a type I IFN on a target cell population comprising increasing the number of functional IFNAR2c receptor chains on the surface of modified cells within the target cell population and then exposing the modified cells to a therapeutically effective amount of a type I IFN, wherein the up-regulation of gene expression of the IFNAR2c gene is accomplished by exposing the modified cells of the target cell population to a small molecule which stimulates the promoter of the IFNAR2c, can not be

classified because the essential structure of the small molecule is not recited.

III. Claims 15-18 and 20, drawn to a method potentiating the anti-growth effects of an effector molecule on a target cell population comprising tumor cells, comprising increasing the number of functional effector molecule receptors on the surface of modified cells within the target cell population and then exposing the modified cells to a therapeutically effective amount of the effector molecule, wherein up-regulation of gene expression of the gene encoding the effector molecule receptor is accomplished by the introduction into the modified cells of an exogenous gene encoding the effector molecule receptor, classified in class 514, subclass 44.

IV. Claims 15-17 and 19-20, drawn to a method potentiating the anti-growth effects of an effector molecule on a target cell population comprising tumor cells, comprising increasing the number of functional effector molecule receptors on the surface of modified cells within the target cell population and then exposing the modified cells to a therapeutically effective amount of the effector molecule, wherein up-regulation of gene expression of the gene encoding the effector molecule receptor is accomplished by exposing modified cells of the target cell population to a small molecule which stimulates the promoter of the gene encoding the

effector molecule receptor, can not be classified because the essential structure of the small molecule is not recited.

V. Claim 21, drawn to a method of potentiating the effects of a type I IFN on a target cell population comprising increasing the number of functional IFNAR1 receptor chains on the surface of modified cells within the target cell population and then exposing the modified cells to a therapeutically effective amount of a type I IFN, can not be classified because the means of increasing the number of functional IFNAR1 receptor chains is unclear and that this method would be subjected to further restrictions.

Claims 1-3, 6-9 and 12-13 link patentably distinct inventions of Groups I-II that lack the unity of invention. This is because the means of increasing the number of functional IFNAR2c receptor chains through an exogenous gene encoding the IFNAR2c polypeptide (Group I) or through a small molecule that stimulates the promoter of the IFNAR2c gene are distinct, and there is no substantial common structural features shared between the exogenous gene and the small molecule. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Similarly, claims 15-17 and 20 link patentably distinct inventions of Groups III-IV that lack the unity of invention. This is because the means of increasing the number of functional functional effector molecule receptors through an exogenous gene encoding the effector molecule receptor (Group III) or through a small molecule that stimulates

the promoter of the gene encoding the effector molecule receptor are distinct, and there is no substantial common structural features shared between the exogenous gene and the small molecule. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-V are distinct each from the others as they are drawn to methods having different starting materials, method steps and therefore they require different technical considerations for achieving the desired end-results. Additionally, the methods of Groups I-V can be carried out independently one from the others. For example, the method in Group I requires the use of an exogenous gene encoding the

IFNAR2c polypeptide for increasing the number of functional IFNAR2c receptor chains which is not required for the methods of Groups II-V. Similarly, the method of Group II requires the use of a small molecule of unknown structure that stimulates the promoter of the IFNAR2c gene that is not required for the practice of any of the methods of Groups I, III to V. The methods of Groups III and IV do not require the use of a gene encoding the IFNAR2c polypeptide or a small molecule that stimulates the promoter of the IFNAR2c gene, respectively. Nor do they require the up-regulation of functional IFNAR1 receptor chains as needed in the method of Group V.

The different inventions above have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements (e.g., different classification), it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species restriction:

Should Applicants elect Group I, claims 1-4 and 6-14 are generic to a plurality of disclosed distinct species comprising:

A specifically named type I IFN listed in the Markush group of claim 6.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 1-4, 6-7 and 10-14 are generic to a plurality of disclosed distinct species of cells involved in a proliferative cell condition comprising:

(a) cancer cells and (b) smooth muscle cells involved in restenosis.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Should Applicants elect Group II, claims 1-3, 5-9 and 12-13 are generic to a plurality of disclosed distinct species comprising:

A specifically named type I IFN listed in the Markush group of claim 6.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Additionally, claims 1-3, 5-7 and 12-13 generic to a plurality of disclosed distinct species of cells involved in a proliferative cell condition comprising:

(a) cancer cells and (b) smooth muscle cells involved in restenosis.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

Gerald G. Leffers Jr.
PATENT EXAMINER
Gerald G. Leffers Jr
A.U. 1636